

Complete Summary

GUIDELINE TITLE

First prescription of the combined oral contraception.

BIBLIOGRAPHIC SOURCE(S)

First prescription of combined oral contraception. J Fam Plann Reprod Health Care 2003 Oct;29(4):209-22. [128 references] [PubMed](#)

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Unintended pregnancy

GUIDELINE CATEGORY

Counseling
Evaluation
Management
Prevention
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine

Obstetrics and Gynecology
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses
Patients
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide information for clinicians on the steps to be taken before providing a woman with her first prescription for combined oral contraception

TARGET POPULATION

Women considering their first prescription of combined oral contraception

INTERVENTIONS AND PRACTICES CONSIDERED

1. Clinical history including medical, sexual, family, and drug history, details of reproductive health, and previous contraceptive use
2. Blood pressure measurement, screening for sexually transmitted infection
3. Assessment of medical eligibility for contraceptive use
4. Counseling and educating patients on risks and benefits of oral combined contraception (COC)
5. Advising women when to start COC in different circumstances, helping them to choose their first COC, and giving instructions regarding missed pills
6. Prescribing COC (refer to the original guideline document for the quick reference guide to COC prescribing)
7. Follow-up visits

MAJOR OUTCOMES CONSIDERED

- Medical eligibility criteria for contraceptive use
- Risks and benefits of combined oral contraception

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Electronic searches were performed for: MEDLINE (CD Ovid version) (1996-2003); EMBASE (1996-2003); PubMed (1996-2003); the Cochrane Library (to 2003), and the US National Guideline Clearing House. The searches were performed using relevant medical subject headings (MeSH), terms, and text words. The Cochrane Library was searched for systematic reviews, meta-analyses, and controlled trials relevant to combined oral contraception. Previously existing guidelines from the Faculty of Family Planning and Reproductive Health Care (FFPRHC), the Royal College of Obstetricians and Gynaecologists (RCOG), the World Health Organization (WHO) and reference lists of identified publications were also searched. Similar search strategies have been used in the development of other national guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Selected key publications were appraised according to standard methodological checklists before conclusions were considered as evidence. Evidence was graded using a scheme similar to that adopted by the Royal College of Obstetricians and Gynaecologists (RCOG) and other guideline development organizations.

Evidence tables (available on the Faculty Web site [www.ffprhc.org.uk]) summarise relevant published evidence on first pill prescription, which was identified and appraised in the development of this Guidance.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Definitions of the grades of recommendation, based on levels of evidence (A-C, Good Practice Point), are provided at the end of the "Major Recommendations" field.

- A holistic approach should be taken when advising women about contraceptive choices (Good Practice Point).
- Contraceptive services should be organised to optimise women's access and choices (Good Practice Point).

Clinical History Taking

1. Women can be advised that they may use combined oral contraception (COC) from menarche to the menopause unless there are medical or other contraindications (Grade C).
2. Women aged more than 35 years who smoke should be advised that the risks of COC use outweigh the benefits (Grade B).
3. Women with a body mass index (BMI) over 30 should be counselled regarding an increased risk of venous thromboembolism (VTE) and consider alternative contraceptive methods (Grade B).

4. Women of any age with focal migraine should be advised that the risks of COC use outweigh the benefits (Grade B).
5. Women using liver enzyme-inducing drugs should be counselled regarding the risks of reduced efficacy (Grade C).
6. Women using liver enzyme-inducing drugs who, having considered other methods, still choose to use COC should be prescribed a regimen containing 50 micrograms ethinyl oestradiol (EE) or mestranol. Additional barrier contraception should be advised until 4 weeks after cessation of the liver enzyme-inducer (Grade C).
7. Women who are established users of non-enzyme-inducing antibiotics (over 3 weeks) do not require additional contraceptive protection when starting COC (Grade C).

Clinicians should take a clinical history, including details of sexual and reproductive health, nonprescription medications, and lifestyle, to be able to advise on eligibility for safe COC use (Good Practice Point).

Women should be advised of the health risks associated with smoking (Good Practice Point).

Examinations and Tests

8. Women with a blood pressure (BP) measurement consistently over 140 mmHg systolic and/or 90 mmHg diastolic should be advised against use of COC (Grade C).
9. A thrombophilia screen is not recommended routinely before prescribing COC (Grade C).
10. For women with a family history of VTE in a first-degree relative under the age of 45 years who, having considered other contraceptive methods, still wish to use COC, a thrombophilia screen should be performed (Grade C).
11. Ideally the risk of sexually transmitted infection (STI) should be assessed and opportunistic Chlamydia testing offered when appropriate, but this is not essential for safe use (Grade C)

The interpretation of a thrombophilia screen should be undertaken in consultation with a haematologist or other expert and in tandem with a detailed family history (Good Practice Point).

Non-Contraceptive Benefits

12. Women may be advised that menstrual pain and blood loss may be reduced with COC use (Grade C).
13. Women may be advised of a reduction in risk of ovarian cancer and ovarian cysts with COC use (Grade B).
14. Women may be advised of a reduction in risk of endometrial cancer with COC use (Grade C).

Risks

15. Women should be advised that although the relative risk of VTE with COC use can increase up to five-fold, in absolute terms the risk is still very low and still considerably lower than the risk of VTE in pregnancy (Grade B).
16. Dianette should be used only for severe acne when oral antibiotics have failed, or for moderately severe hirsutism. It should be discontinued 3 to 4 months after the condition treated has resolved (Grade C).
17. Women should be advised of a very small increase in the absolute risk of ischaemic stroke with COC use (Grade B).
18. Healthy non-smokers can be advised that they have no increased risk of myocardial infarction (MI) with COC use (Grade B).
19. Women with and without a family history of breast cancer may be advised that any increased risk of breast cancer with COC use is likely to be small (Grade B).
20. Women should be advised that OC use for less than 5 years does not increase the risk of cervical cancer, but the risk increases with more than 5 years' use (Grade B).
21. Women can be advised that there is no evidence of weight gain with COC use (Grade A).
22. Women should be advised that breakthrough bleeding (BTB) can occur with COC use but, in the absence of missed or late pills, vomiting, or drug interactions, has not been shown to be a measure of efficacy (Grade B).

Women should be provided with information on warning signs of VTE, which should prompt immediate medical consultation (Good Practice Point).

Women should be encouraged to participate in the National Health Service (NHS) cervical screening programme to reduce their risk of cervical cancer (Good Practice Point).

Women should be advised of possible causes of unscheduled bleeding, such as missed and late pills, STI, vomiting, and drug interactions, and when to seek medical advice (Good Practice Point).

What information do women need to use COC appropriately?

When to start COC in different circumstances?

Circumstances for COC start	When to start COC	Additional contraceptive protection required
Women having menstrual cycles	Start COC up to and including Day 5	None
	At any other time if it is reasonably certain that woman is not pregnant	For 7 days
Amenorrhoeic	COC can be started at any time, if it is reasonably certain that she is not pregnant.	For 7 days
Breastfeeding	If more than 6 months	For 7 days

Circumstances for COC start	When to start COC	Additional contraceptive protection required
	postpartum and amenorrhoeic, COC can be given as for other amenorrhoeic women.	
	If she is more than 6 months postpartum and her menstrual cycles have returned, she can start COC as for other women having menstrual cycles.	As for other women having menstrual cycles
Switching from other hormonal methods (other than the intrauterine system [IUS])	COC can be started immediately if she has been using her hormonal method consistently and correctly, or if it is reasonably certain she is not pregnant. There is no need to wait for her next menstrual period.	None
	If her previous method was an injectable, she should start COC when the repeat injection would have been given.	None
Switching from a non-hormonal method (other than the intrauterine device [IUD])	Start COC up to and including Day 5.	None
	At any other time if it is reasonably certain that she is not pregnant	For 7 days
Switching from an IUD or IUS	COC can be started up to and including Day 5 after the start of menstrual bleeding. IUD/IUS can be removed at that time	None
	COC can be started at any other time, if it is reasonably certain she is not pregnant:	
	<ul style="list-style-type: none"> If she has been sexually active in this menstrual cycle 	The IUD/IUS will provide contraceptive protection and should be removed with the next bleed
	<ul style="list-style-type: none"> If she has not been sexually active in this menstrual cycle 	For 7 days or alternatively if the additional contraceptive protection is to be provided by the IUD/IUS it should be removed at the time of her

Circumstances for COC start	When to start COC	Additional contraceptive protection required
		next bleed
	<ul style="list-style-type: none"> If she is amenorrhoeic or has irregular bleeding, COC can be started as advised for other amenorrhoeic women. 	As for other amenorrhoeic women

23. Women should be advised that COC works by inhibition of ovulation and also has effects on cervical mucus and endometrium (Grade B).
24. Women should be advised that COC can be over 99% effective at preventing pregnancy, if used consistently and correctly (Grade B).
25. Ideally COC should be started on Day 1 of the menstrual cycle but women may be advised that COC can be started up to and including Day 5 of the cycle without the need for additional contraception (Grade C).
26. Women should be advised that COC can be started at any other time in the cycle if there has been no risk of pregnancy, but additional contraception is required for the first 7 days (Grade C).
27. Women who are not breastfeeding should be advised to start COC after Day 21 postpartum (Grade C).
28. Women should be advised that, ideally, COC should be started on the day of a first- or second-trimester termination of pregnancy (TOP), but can be started within 7 days to provide immediate contraceptive protection (Grade C).
29. Women should be advised that, routinely, COCs should be taken within 12 hours of the same time every day for 21 consecutive days (Grade C).
30. Women should be advised that contraception is still provided during the routine seven hormone-free days (Grade B).
31. Women should be advised to return for a pregnancy test if, following missed or late pills, vomiting or severe diarrhoea, or use of any new drug, there is a very light or no withdrawal bleed (Grade C).
32. Women using non-enzyme-inducing, broad-spectrum antibiotics for short courses (<3 weeks) should be advised to use additional contraception during the course and for 7 days afterwards (Grade C).
33. Women using short courses of rifampicin for prophylaxis should be advised to use additional contraception during the course and for 4 weeks afterwards (Grade C).

Women should be provided with appropriate written and verbal instruction regarding rules for missed or late pills, vomiting or severe diarrhoea, and the use of new medications (Good Practice Point).

Women should be advised to use condoms in addition to COC if at risk of STI (Good Practice Point).

Women may be given advice regarding "tricycling" packs of COC to avoid withdrawal bleeds (Good Practice Point).

Women may be advised how to adjust the pill-free interval to avoid weekend withdrawal bleeds (Good Practice Point).

Women should be advised when COC is being recommended outside the product license, (for example, tricycling) (Good Practice Point).

How can clinicians help women choose their first COC?

34. A monophasic COC containing 30-35 micrograms ethinyl estradiol (EE) with a low dose of either norethisterone or levonorgestrel is a suitable first-line option (Grade C).

There are no COCs that cannot be used first-line after counselling and the preference of the woman should be taken into consideration when prescribing COC (Good Practice Point).

35. COC can be prescribed, without parental consent, to a young woman aged less than 16 years if she is assessed to be competent to make an informed choice (Grade C).
36. Health professionals dealing with young people should be aware of local procedures for dealing with issues relating to child protection, confidentiality, and disclosure (Grade C).

What follow-up arrangements are appropriate following first prescription of COC?

37. In the absence of special problems, women can be given up to 12 months' supply of COC at the first visit and encouraged to return at any time if problems arise (Grade C).
38. Appropriate written information should be provided to all women prescribed COC (Grade B).

A follow-up visit 3 months after the initial COC consultation allows further instruction and assessment of any problems (Good Practice Point).

Women should be provided with telephone numbers of appropriate local and national helplines providing advice on contraception and sexual health (Grade C).

Definitions

Grades of Recommendation based on levels of evidence as follows:

A: Evidence based on randomised controlled trials (RCTs)

B: Evidence based on other robust experimental or observational studies

C: Evidence is limited but the advice relies on expert opinion and has the endorsement of respected authorities

Good Practice Point where no evidence exists but where best practice is based on the clinical experience of the Expert Group

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

General Potential Benefits

- Improved knowledge of the steps to be taken before providing a woman with her first prescription for combined oral contraception

Specific Benefits

Non-contraceptive benefits of combined oral contraception (COC)

- Reduction in menstrual pain and blood loss
- Reduction in risk of ovarian cancer and ovarian cysts, endometrial cancer, and colonic cancer
- Reduction in the incidence of hip fracture, acne lesions, rheumatoid arthritis, benign breast disease

POTENTIAL HARMS

Risks of Combined Oral Contraception (COC)

- Increase in relative risk of venous thromboembolism (three-fold increase with levonorgestrel and norethisterone COCs and five-fold increase with desogestrel and gestodene COCs); Dianette has shown a four-fold increase in the risk of venous thromboembolism compared with COC containing levonorgestrel. Dianette should only be used in women with severe acne or moderately severe hirsutism and should be withdrawn 3 to 4 months after the treated condition has resolved or if there is no improvement in symptoms.
- Two-fold increase in ischemic stroke
- A small increase in the risk of breast cancer
- Risk of cervical cancer increases with more than 5 years' use of COC
- Breakthrough bleeding can occur with COC
- Liver enzyme-inducing drugs may reduce the efficacy of COC

Risks associated with COC usually outweigh the benefits in the following circumstances:

- Breastfeeding - between 6 weeks and 6 months postpartum and primarily breastfeeding
- Postpartum - Less than 21 days
- Smoking - aged more than 35 years and smoking fewer than 15 cigarettes/day
- Hypertension - a history of hypertension when blood pressure (BP) cannot be measured, adequately controlled BP where it can be measured, elevated BP 140-159 mmHg systolic and 90-99 mmHg diastolic
- Migraine - without focal symptoms in women aged 35 years or older
- Breast disease - past history of breast cancer and no evidence of recurrence for 5 years
- Gallbladder disease - symptomatic medically treated or current
- Cirrhosis - mild compensated
- Commonly used drugs which affect liver enzymes - antibiotics (rifampicin and griseofulvin) and certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone)

CONTRAINDICATIONS

CONTRAINDICATIONS

According to World Health Organization (WHO) eligibility criteria for contraceptive use combined oral contraception should not be used in the following circumstances:

- Breastfeeding - Less than 6 weeks postpartum
- Smoking - aged 35 years or older and smoking more than 15 cigarettes/day
- Cardiovascular disease - multiple risk factors for arterial cardiovascular disease
- Hypertension - blood pressure (BP) higher than 160 mmHg systolic, higher than 100 mmHg diastolic (Clinical Effectiveness Unit [CEU] recommendation is over 140 mmHg systolic and 90 mmHg diastolic)
- Venous thromboembolism (VTE) - current or past history
- Major surgery with prolonged immobilisation
- Current ischaemic heart disease
- Stroke
- Valvular heart disease - complicated by pulmonary hypertension, atrial fibrillation, history of subacute bacterial endocarditis
- Migraine headaches - with focal neurological symptoms at any age
- Breast disease - current breast cancer
- Diabetes - nephropathy, retinopathy, neuropathy or other vascular disease, or diabetes of >20 years duration
- Cirrhosis - severe decompensated
- Liver tumours - benign and malignant

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Staff Training/Competency Material

For information about [availability](#), see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

First prescription of combined oral contraception. J Fam Plann Reprod Health Care 2003 Oct;29(4):209-22. [128 references] [PubMed](#)

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Oct

GUIDELINE DEVELOPER(S)

Faculty of Family Planning and Reproductive Health Care - Professional Association

SOURCE(S) OF FUNDING

Faculty of Family Planning and Reproductive Health Care

GUIDELINE COMMITTEE

Clinical Effectiveness Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Clinical Effectiveness Unit (CEU): Dr Gillian Penney (Director), Dr Susan Brechin (Co-ordinator); and Alison de Souza (Research Assistant)

Clinical Effectiveness Committee: Professor Anna Glasier (Chair); Dr Chris Wilkinson (ex-officio); Dr David Hicks; Dr Joanne Protheroe; Dr Jo Power; Ms Toni Belfield; Catronia Sutherland

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

Print copies: Available from the Faculty of Family Planning and Reproductive Health Care, 27 Sussex Place, Regent's Park, London NW1 4RG

AVAILABILITY OF COMPANION DOCUMENTS

Discussion points and questions for the first prescription of combined oral contraception developed by the Faculty of Family Planning and Reproductive Health are available at the end of the original guideline document.

Electronic copies: Available in Portable Document Format (PDF) from the [Faculty of Family Planning and Reproductive Health Care Web site](#).

PATIENT RESOURCES

None available

NGC STATUS

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